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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,162	03/08/2001	Robert Getts	4081.005	6213

7590 03/05/2004

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/802,162	GETTS, ROBERT	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on September 30, 2003 has been entered and considered.

2. The instant application is filed on March 8, 2001, which claims priority to a provisional application 60/187,681 filed on March 8, 2000.

3. Claims 1-2, 18-19 are amended. New claims 20-26 are added. Thus claims 1-26 are pending in this application.

New Grounds of rejections necessitated by Amendment

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-4, 10-11, 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-30 of copending Application No. 10/234,069 ('069). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a method for detection and assay on a microarray comprising (a) contacting first component (cDNA having a capture sequence) and second component (having dendrimer having a label) simultaneously or in a pre-

hybridized form with a microarray having plurality of features each containing a particular nucleotide sequence (b) incubating the mixture at a time sufficient to enable the first nucleotide sequence of the said microarray bind to the first component, resulting in a hybridization pattern. Further, the claims in the copending application ('069) disclose that the method comprises (forming first component comprising cDNA reagent by contacting with RT primer having the capture sequence; purging excess unhybridized RT primer, and unattached dendrimer; detecting the signal and hybridization pattern. The claims in the co-pending application ('069) encompass the instant method limitations and obvious over the claims in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dellinger et al. (USPN. 5,853,993) in view of Schena et al. (Science, Vol. 270, pp. 467-470, 1995).

Dellinger et al. teach a method claim 1 and 18, for detecting nucleic acids on a solid support, wherein the method comprises

1) (a) taking an immobilized capture probe (see column 4, lines 50-67, column 3, lines 44-50);

(b) taking a first component comprising DNA reagents (target analyte) having a capture sequence (homopolymeric tailing or Poly A or poly U tail) (see column 3, lines 20-24, column 5, lines 4-14);

(c) taking a second component (reporter probe) comprising a dendrimer (hairpin reporter probes) having at least on first arm comprising label and at least one second arm having a second nucleotide sequence which is complementary to the homopolymeric region on the target analyte (see column 5, lines 23-32, column 10, lines 21-49);

wherein said second sequence of dendrimer binds with the capture sequence (homopolymeric region) of the target analyte forming reporter-analyte hybrid (see column 1, lines 53-61);

2) mixing said first and second components at a temperature and for a time sufficient to enable said first component to bind with the second component (see column 1, lines 53-61, column 10, lines 51-57);

3) incubating this mixture with said immobilized capture probe to enable the first nucleotide sequence to bind to said first component, generating a hybridization pattern (see column 1, lines 61-63, column 10, lines 55-60);

with regard to claim 8, Dellinger et al. teach that the time sufficient to enable the second and first component is 1hour to 3hours (see column 10, lines 52-55);

with regard to claim 10, Dellinger et al. disclose that the detection of the hybridization signal by scanning the microarray using fluoroimager instrument (see column 10, lines 61-62);

With regard to claim 11, Dellinger et al. also disclose washing the microarray to purge unattached denrimers after hybridization reaction (see column 10, lines 58-60, column 9, lines 30-34);

With regard to claim 13, Dellinger et al. teach that the method comprises hybridization buffer (see column 10, lines 51-55);

With regard to claims 20-21, the mixing of first and second components is conducted on the said microarray or in solution (off microarray) (see column 4, lines 50-66).

However, Dellinger et al. did not teach a microarry with plurality of probes and RT-PCR components.

Schena et al. teaches a method for quantitative gene expression with a cDNA microarray (see page 467, summary, page 469, column 3, paragraph 1) wherein Schena et al. teaches (1) incubating a cDNA array with a first component comprising cDNA having a fluorescent label obtained from mRNA (see page 467, column 3, paragraph 2, page 470, column 1, ref. 5); (2) mixing said first component with said microarray at a temperature and for a time sufficient to enable the nucleotide sequence on the microarray binds to the first component resulting in the generation of a hybridization pattern on the microarray (see page 467, column 3, paragraph 2, page 470, column 1, ref 6) Schena et al. also teach (i) cDNA reagent comprising the step of contacting target sample mRNA with oligo (dT) primer, reverse transcriptase and labeled dNTPs under conditions sufficient for initiating reverse transcription of said mRNA in to cDNA (see page 467, column 3, paragraph 2, page 470, column 1, ref 5); (ii) hybridization wash solutions including varying concentrations of SSC (1- 0.1X) and SDS (0.1%), hybridization conditions including hybridization temperatures ranging from 25^0 - 65^0 C in a hybridization chamber (see

page 467, column 3, paragraph 2); incubating the said mixture for 18 hours to enable the binding of said first component with the particular nucleotide sequence on the said microarray (see page 467, column 3, paragraph 2, page 470, column 1, ref. 6).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for detection of target analyte as taught by Dellinger et al. with a method using cDNA microarray hybridization as taught by Schena et al. to achieve expected advantage of developing an improved high-throughput detection method because Schena et al. taught high throughput robotic system for monitoring gene expression and quantitation of expression measurements of the corresponding genes (see abstract on page 270).

Further selection of specific hybridization buffers, hybridization conditions and automation of hybridization assay represents routine optimization with regard to hybridization, which routine optimization parameters are explicitly recognized in Schena et al. As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to is cover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the hybridization buffers or conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of Dellinger et al. with Schena et al. in order to achieve the expected advantage of developing a high throughput assay method for detecting a target nucleic acid because the addition of the limitation as taught by Schena et al. would reduce time and reagent consumption and improve detection of a large number of targets

at given time.

Response to arguments

6. Applicants' response to the office action is fully considered and found persuasive.

7. With regard to the rejection made in the previous office action under provisional obviousness-type double patenting, Applicants' arguments are fully considered, however, the rejection is maintained herein, because Applicants did not submit a terminal disclaimer to over come the rejection.

8. With regard to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments and amendment are fully considered and the rejection is moot in view of new grounds of rejections.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
March 2, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER